

Practitioner's Docket No.

2544/111

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Luscombe et al.

Application No.: 10/019,802

Group No.: 1621

Filed: 05/06/2002

Examiner: Davis, Brian J.

For: Therapeutic Agents

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

TRANSMITTAL OF SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT  
BEFORE MAILING DATE OF EITHER A FINAL ACTION  
OR NOTICE OF ALLOWANCE (37 C.F.R. SECTION 1.97(c))

NOTE: An information disclosure statement shall be considered by the Office if filed . . . before the mailing date of either (1) a final action under Section 1.113 or (2) a notice of allowance under Section 1.311, whichever occurs first, provided the statement is accompanied by either a statement as specified in paragraph (e) of Section 1.97 or the fee set forth in Section 1.17(p).

NOTE: "If a final action or notice of allowance is mailed in an application and later withdrawn, the application will be considered as not having had a final action or notice of allowance mailed for purposes of considering an information disclosure statement." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

NOTE: "If information submitted during the period set forth in 37 C.F.R. 1.97(c) with a certification is used in a new ground of rejection on unamended claims, the next Office action will not be made final since in this situation it is clear that

CERTIFICATE OF MAILING/TRANSMISSION (37 C.F.R. SECTION 1.8(a))

I hereby certify that, on the date shown below, this correspondence is being:

MAILING

FACSIMILE

☒ deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

☐ transmitted by facsimile to the Patent and Trademark Office (703) \_\_\_\_-\_\_\_\_.

Date: December 29, 2004

Signature

Barbara J. Carter, Ph.D.

(type or print name of person certifying)

(Transmittal of Information Disclosure Statement Before Mailing Date of Final Action or Notice of Allowance--page 1 of 3)

The PTO did not receive the following

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\$790

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*applicant has submitted the information to the office promptly after it has become known and the information is being submitted prior to a final determination on patentability by the Office. However, the information submitted with a certification can be used in a new ground of rejection and the next Office action made final, [i]f the new ground of rejection was necessitated by amendment of the application by applicant. Where the information is submitted during this period with a fee, the examiner may use the information submitted, e.g., printed publication or evidence of public use, and make the next Office action final whether or not the claims have been amended, provided that no other new ground of rejection which was not necessitated by amendment to the claims is introduced by the examiner. See MPEP 706.07(a). If a new ground of rejection is introduced that is neither necessitated by an amendment to the claims nor based on the information submitted with the fee set forth in 37 C.F.R. 1.17(p), the Office action shall not be made final." Notice of April 20, 1992 (1138 O.G. 37-41, 39).*

**WARNING:** "A petition for suspension of action to allow applicant time to submit an information disclosure statement will be denied as failing to present good and sufficient reasons, since 37 C.F.R. 1.97 provides adequate recourse for the timely submission of prior art for consideration by the examiner." Notice of July 6, 1992 (1141 O.G. 63).

### **TIME OF TRANSMITTAL OF ACCOMPANYING SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

1. The information disclosure statement transmitted herewith is being filed **after** three months of the filing date of this national application or the date of entry of the national stage as set forth in Section 1.491 in an international application or after the mailing date of the first Office action on the merits, whichever event occurred last but **before** the mailing date of either:

- (1) a final action under Section 1.113 or
- (2) a notice of allowance under Section 1.311,

whichever occurs first.

### **STATEMENT OR FEE**

2. Accompanying this transmittal is

*(check either A or B below)*

A. ☐ a statement as specified in 37 C.F.R. Section 1.97(e).

**OR**

B. ☒ the fee set forth in 37 C.F.R. Section 1.17(p) for submission of an information disclosure statement under Section 1.97(c). (\$180.00).

### **FEE PAYMENT**

*(complete this item, if applicable)*

3. Applicant elects the option to pay the fee set forth in 37 C.F.R. Section 1.17(p) for submission of an information disclosure statement under Section 1.97(c) (\$180.00).

Fee due \$ \_\_\_\_\_

**METHOD OF PAYMENT OF FEE**

4.

☒ Attached is a check in the amount of \$ 180.00.

☐ Charge Account No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_.

A duplicate of this request is attached.


If any additional fees are due, please charge Account #19-4972.

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\_\_\_\_\_  
SIGNATURE OF PRACTITIONER

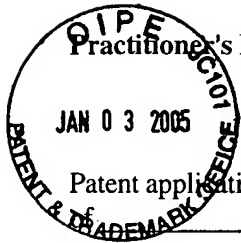
Barbara J. Carter, Ph.D.

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Boston, MA 02110



Practitioner's Docket No.

2544/111

PATENT

JAN 03 2005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent application

Inventor(s)

for

Title of invention

the specification of which is being transmitted herewith

OR

In re application of: Luscombe et al.

Application No.: 10/019,802

Group No.: 1621

Filed: 05/06/2002

Examiner: Davis, Brian J.

For: Therapeutic Agents

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P.O. Box 1450

Alexandria, VA 22313-1450

(Information Disclosure Statement--page 1 of 6)

**CERTIFICATION UNDER 37 C.F.R. SECTIONS 1.8(a) and 1.10\***

(When using Express Mail, the Express Mail label number is *mandatory*;  
Express Mail certification is optional.)

I hereby certify that, on the date shown below, this correspondence is being:

**MAILING**

☒ deposited with the United States Postal Service in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

**37 C.F.R. SECTION 1.8(a)**

**37 C.F.R. SECTION 1.10\***

☒ with sufficient postage as first class mail.

☐ as "Express Mail Post Office to Addressee"

Mailing Label No. \_\_\_\_\_ (mandatory)

**TRANSMISSION**

☐ transmitted by facsimile to the Patent and Trademark Office.

Signature

Date: December 29, 2004

Barbara J. Carter, Ph.D.

(type or print name of person certifying)

**\*WARNING:** Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. section 1.10(b).  
"Since the filing of correspondence under section 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable C.F.R.e, requests for waiver of this requirement will *not* be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

## SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

**NOTE:** "An information disclosure statement shall be considered by the Office if filed by the applicant:

- (1) Within three months of the filing date of a national application;
- (2) Within three months of the date of entry of the national stage as set forth in section 1.491 in an international application; or
- (3) Before the mailing date of a first Office action on the merits, whichever event occurs last." 37 C.F.R. section 1.97(b).

**NOTE:** "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. section 1.56(a).

"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) each inventor named in the application;
- (2) each attorney or agent who prepares or prosecutes the application; and
- (3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 C.F.R. section 1.56(c).

**NOTE:** The "duty as described in section 1.56 will be met so long as the information in question was cited by the Office or submitted to the Office in the manner prescribed by sections 1.97(b) - (d) and 1.98 before issuance of the patent." Notice of January 9, 1992, 1135 O.G. 13-25 at 17.

**WARNING:** "No information disclosure statement may be filed in a provisional application." 37 C.F.R. section 1.51(b).

### List of Sections Forming Part of This Information Disclosure Statement

The following sections are being submitted for this Information Disclosure Statement:

(check sections forming a part of this statement: disC.F.R.d unused sections and number pages consecutively)

1. ☒ Preliminary Statements
2. ☒ Forms PTO/SB/08A and 08B (substitute for Form PTO-1449)
3. ☐ Statement as to Information Not Found in Patents or Publications
4. ☐ Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted
5. ☐ Cumulative Patents or Publications
6. ☒ Copies of Listed Information Items Accompanying This Statement
7. ☐ Concise Explanation of Non-English Language Listed Information Items
  - 7A. ☐ EPO Search Report
  - 7B. ☐ English Language Version of EPO Search Report
8. ☐ Translation(s) of Non-English Language Documents
9. ☐ Concise Explanation of English Language Listed Information Items (Optional)
10. ☒ Identification of Person(s) Making This Information Disclosure Statement

(complete the following, if appropriate)

Sections \_\_\_\_\_, respectively, have been continued on ADDED PAGE(S).

**NOTE :** "Once the minimum requirements are met, the examiner has an obligation to consider the information." Notice of April 20, 1992 (1138 O.G. 37-41, 37).

## **Section 1. Preliminary statements**

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. section 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.



SECTION 2. FORMS PTO/SB/08A and 08B (formerly Form PTO-1449)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Luscombe, et al.

Attorney Docket: 2544/111

Serial No: 10/019,803

Art Group Unit: 1621

Date Filed: 05/06/2002

Examiner Name: Davis, Brian J.

Invention: Therapeutic Agents

LIST OF PATENTS AND PUBLICATIONS FOR  
APPLICANT'S SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

U.S. PATENT DOCUMENTS					
Examiner Initials	Reference Number	Document Number	Issue Date	Inventor	Class/Subclass
	AC	US 5,047,432	Sept. 10, 1991	Housley et al.	A61K 31/135

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Reference Number	Country Code	Document Number	Publication Date	Patentee or Applicant	Class/Subclass
	AD	EP	0 282 206 B1	Nov. 07, 1990	The Boots Company PLC	A61K 31/135
	AE	EP	0 111 994 B1	Sept. 27, 1983	The Boots Company PLC	C07 C 87/455
	AF	GB	2 098 602 A	Apr. 1, 1981	Therapeutic Agents	C07 C 87/34

Examiner Signature: \_\_\_\_\_

Date Considered: \_\_\_\_\_

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation *if not* in conformance and not considered. Include copy of this form with next communication to applicant.

## Section 6. Copies of Listed Information Items Accompanying This Statement

*NOTE: 37 C.F.R. section 1.98(a)(2) requires that any information disclosure statement filed under section 1.97 shall include: "A legible copy of: (i) Each U.S. and foreign patent; (ii) Each publication or that portion which caused it to be listed; and (iii) All other information or that portion which caused it to be listed, except that no copy of a U.S. patent application need be included . . ."*

*NOTE: The wording in section 1.98(a)(2)(iii) makes it clear that the requirement to submit a copy of each item of information listed in an information disclosure statement does not apply to the citation of a U.S. patent application. Notice of January 9, 1992, 1135 O.G. 13-25, at 14.*

Legible copies of all items listed in Forms PTO/SB/08A and 08B (substitute for Form PTO-1449) accompany this information statement.

*(complete the following, if applicable)*

☒ Exception(s) to above:

☐ Items in prior application, from which an earlier filing date is claimed for this application, as identified in Section 4.

☐ Cumulative patents or publications identified in Section 5.

U.S. patent citations are not included pursuant to 37 CFR 1.98 9(a)(2)(i) and 37 CFR 1.491(b), in which the USPTO waived the requirement for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003 and for all international applications that have entered the national stage under 35 USC § 371 after June 30, 2003.

**Section 10. Identification of Person(s) Making This Information Disclosure Statement**

The person making this certification is

*(check each applicable item)*

- (a) ☐ the inventor(s) who signs below

\_\_\_\_\_  
**SIGNATURE OF INVENTOR**

\_\_\_\_\_  
*(type name of inventor who is signing)*

- (b) ☐ an individual associated with the filing and prosecution of this application (37 C.F.R. section 1.56(c))

\_\_\_\_\_  
**SIGNATURE OF INVENTOR**

\_\_\_\_\_  
*(type name of inventor who is signing)*

- (c) ☒ the practitioner who signs below on the basis of the information:

*(check each applicable item)*

☐ supplied by the inventor(s).

☐ supplied by an individual associated with the filing and prosecution of this application. (37 C.F.R. section 1.56(c)).

☒ in the practitioner's file.

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02544/00111 354631.1

  
\_\_\_\_\_  
**SIGNATURE OF PRACTITIONER**

Barbara J. Carter, Ph.D.

*(type or print name of practitioner)*

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